HCA Healthcare | Clinical Operations Group

DEPARTMENT: HCA Healthcare Clinical Operations Group	**POLICY DESCRIPTION:** Patient Restraint/ Seclusion
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SCOPE

This policy/procedure applies to healthcare professionals operating within HCA Healthcare facilities that have responsibility for ordering, assessing, care planning, restraining, or monitoring the restrained patient. This policy is applicable to all age groups of patients, including neonates.

PURPOSE:

1. To protect the dignity and safety of inpatients, outpatients, staff and visitors through safe restraint processes.[1]
2. To identify patients at risk for restraint or seclusion and provide alternatives to restraint use.
3. To provide guidelines for use of least restrictive interventions to avoid restraint or seclusion use.
4. To define the procedure to be followed when all alternatives have been exhausted and proven ineffective, and restraints are necessary to maintain patient safety.
5. To define staff training requirements related to safe restraint or seclusion processes. Refer to Appendix A for training requirements.

POLICY:

HCA Healthcare is dedicated to fostering a culture that supports a patient's right to be free from restraint or seclusion. Restraint or seclusion use will be limited to clinically-justified situations, and the least restrictive restraint will be used with the goal of reducing, and ultimately eliminating, the use of restraints or seclusion. The facility Chief Nursing Officer (CNO), Ambulatory Surgery Center (ASC) Administrator and ASC Nurse Manager provides leadership and organizational accountability for monitoring the safety, appropriateness and necessity of restraint or seclusion use.

PROCEDURE:

1. **Assessment for Risk for Restraint**
   a. The Registered Nurse (RN) performs an assessment for risk for restraint or seclusion when a patient exhibits behavior that may place the patient at risk for restraint or seclusion. This risk assessment includes:[2]
      1) Does the patient have a medical device?
      2) Does the patient understand the need to not remove the device?
      3) Is the patient required to be immobile?
      4) Does the patient understand the need to remain immobile?
      5) Is the patient exhibiting aggressive, combative or destructive behavior?
      6) Does this behavior place the patient/staff/others in immediate danger?

   b. The assessment for the risk for restraint or seclusion also includes:
      1) Patients who arrive in restraint.
      2) Patients in restraint who have recovered from the effects of anesthesia and are awaiting transfer to a bed.

Note: Patients in the NICU and nursery are excluded from the assessment for risk for restraint.

2. **Alternatives to Restraint or Seclusion**
Patients that are determined to be at risk for restraint or seclusion will have alternatives initiated promptly. Appendix B contains a listing of alternatives to restraint or seclusion.

3. **Determination That Alternatives to Restraint or Seclusion Have Failed**
The RN determines that alternatives to restraint or seclusion have failed and that the patient will be safer in restraints than continuing without restraint.

4. **Second Tier of Review[2]**
A member of nursing administration/management (e.g., nursing supervisor/manager, charge nurse, manager/director, CNO, etc.) will review the need for restraint or seclusion with the RN who has determined that the patient requires restraint or seclusion. The second tier of review will occur with the initial application of restraint or seclusion. Renewals of restraint or seclusion orders do not require a second tier of review. The review includes:
   a. Alternatives attempted
   b. Reason for restraint or seclusion
   c. Least restrictive type of restraint
   d. Staff's knowledge of the cause of patient behavior (physiological, psychological, environmental, medication)
   e. Appropriate restraint for vulnerable patient populations
   f. Staffing available for monitoring
   g. Affirmation of partnering to meet the patient needs with safety and compassion

   Note: In an emergency application of the restraint or seclusion, the above review will be done immediately after the application of restraint.

5. **Order for Restraint or Seclusion**
   a. An order for restraint or seclusion must be obtained from a physician or other licensed practitioner who is acting within their State Scope of Practice, authorized by State law as having authority for ordering restraints, and is responsible for the care of the patient prior to the application of restraint or seclusion.[3] A resident who is authorized by State law and the hospital's residency program to practice as a physician may order restraints. The order must specify clinical justification for the restraint or seclusion, the date and time ordered, the

duration of use, the type of restraint to be used and behavior-based criteria for release.

1) An order for restraint or seclusion may not be written as a standing order, protocol or as a PRN or "as needed" order.[4]
2) If a patient was recently released from restraint or seclusion and exhibits behavior that can only be handled through the reapplication of restraint or seclusion, a new order is required.[3]

b. If a telephone order is required, the RN must enter the order in CPOE while the physician or other licensed practitioner, authorized by State law to order restraints, is on the phone and read-back the order to verify accuracy.[5] The order must specify clinical justification for the restraint, the date and time ordered, the duration of use, the type of restraint and behavior-based criteria for release.

c. The treating physician is to be notified as soon as possible if another physician or licensed practitioner, authorized by State law to order restraints, (e.g., on-call physician) orders the restraint.

d. When a physician or other licensed practitioner, authorized by State law to order restraints, is not available to issue a restraint or seclusion order, an RN with demonstrated competence may initiate restraint or seclusion use based upon face-to-face assessment of the patient. In these emergency situations, the order must be obtained during the emergency application or immediately (within minutes) after the restraint or seclusion is initiated.[3]

5A. Order for Restraint with Non-Violent or Non-Self-Destructive Behavior

a. Initial restraint order: An initial order for restraint must not exceed 24 hours, must specify clinical justification for the restraint, the date and time ordered, the duration of use, the type of restraint and behavior-based criteria for release.

1) An initial order for restraint must not exceed 24 hours. The physician or licensed practitioner may order a shorter period of time.
2) Staff assess, monitor, and re-evaluate the patient regularly and release the patient from restraint when criteria for release are met.

b. To continue restraint use beyond the initial order duration, the physician or other licensed practitioner must see the patient, perform a clinical assessment and determine if continuation of restraint is necessary.

c. Renewal restraint order: If reassessment indicates an ongoing need for restraint, a renewal restraint order must be entered into the medical record within 24 hours of the initial restraint order. Subsequent renewal orders will be entered for each calendar day by the physician or other licensed practitioner, authorized by State law to order restraints.[2]

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5B. Order for Restraint with Violent or Self-Destructive Behavior[7, 8, 20]

a. Orders for restraint or seclusion must be time limited and must specify clinical justification for the restraint or seclusion, the date and time ordered, duration of restraint or seclusion use, the type of restraint, and behavior-based criteria for release. Orders for restraint or seclusion must not exceed:
   1) Four hours for adults, aged 18 years and older
   2) Two hours for children and adolescents aged nine to 17 years, or
   3) One hour for children under nine years.
      i. The time frames specified are maximums. A physician or other licensed practitioner, authorized by State law, may order a shorter period of time.
      ii. Staff assess, monitor, and re-evaluate the patient regularly and release the patient from restraint or seclusion when criteria for release are met.

b. To continue restraint or seclusion beyond the initial order duration, the RN determines that the patient is not ready for release and calls the ordering physician or licensed practitioner, authorized by State law to order restraints, to obtain a renewal order. Renewal orders for restraint/seclusion may not exceed:
   1) Four hours for adults, aged 18 years or older
   2) Two hours for children and adolescents aged nine to 17 years, or
   3) One hour for children under nine years.

c. Orders may be renewed according to time limits above for a maximum of 24 consecutive hours. Every 24 hours, unless state law is more restrictive, a physician or other authorized licensed practitioner primarily responsible for the patient's care conducts a face-to-face evaluation of the patient before writing a new order for restraint or seclusion.

d. When the physician or other licensed practitioner renews an order or writes a new order authorizing the continued use of restraint or seclusion for violent or destructive behavior, there must be documentation in the patient's medical record that describes the findings of the physician's or other licensed practitioner's re-evaluation supporting the continued use of restraint or seclusion.

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6. Application of Restraints

a. Restraints are applied by staff with demonstrated competence in restraint application.
b. The patient is informed of the purpose of the restraint or seclusion and the criteria for removal.
c. The patient's family is informed of restraint or seclusion use, the purpose of the restraint or seclusion and the criteria for removal.
d. Products including such features as non-locking synthetic, quick release (Velcro or buckle), and with the ability to be cleaned with antimicrobial cleaning product between uses may be used. No synthetic leather, locking or hard restraint such as handcuffs will be permitted for use in the application of restraints for violent or self-destructive behaviors. Additional non-approved restraint devices include spit sock hoods, vest restraints and full body net restraint devices.

7. Monitoring the Patient in Restraints or Seclusion[2, 8]

a. Patients are assessed by an RN immediately after restraints or seclusion are initiated to assure safe application/initiation of the restraint or seclusion.
b. An RN will assess the patient at least every two hours. The assessment will include where appropriate:
    1) Signs of injury associated with restraint, including circulation of affected extremities
    2) Respiratory and cardiac status
    3) Psychological status, including level of distress or agitation, mental status and cognitive functioning
    4) Needs for range of motion, exercise of limbs and systematic release of restrained limbs are being met
    5) Hydration/nutritional needs are being met
    6) Hygiene, toileting/elimination needs are being met
    7) The patient's rights, dignity, and safety are maintained
    8) Patient's understanding of reasons for restraint and criteria for release from restraint
    9) Consideration of less restrictive alternatives to restraint
c. More frequent monitoring and notification of the ordering physician or licensed practitioner occurs when:
    1) Patient's medical and emotional needs and health status change
    2) The type and design of the device or intervention poses increased risk
    3) The level of patient agitation/distress at being placed in restraint as evidenced by an escalation of behavior
    4) Evidence of injury related to use of restraint
d. A trained staff member monitors each patient in restraint or seclusion at least three times an

hour for safety, and to confirm that the patient's rights and dignity are maintained. This check will be documented in either electronic record or on paper. If a paper checklist is used as a summary, recording time and observation from each of the three times an hour check, may be recorded at the end of the shift and the checklist scanned into the EHR/HPF patient record.

e. For patients under continuous or frequent in-person observations (e.g., ICU, PACU, etc.), or continuous audio and/or video monitoring safety checks occur in real time on an ongoing basis, documentation that safety, rights, and dignity were maintained for the defined period of time may be entered/attested to at end of the shift.
f. Monitoring is based on the individual needs of the patient. Variables of the patient's condition, cognitive status, and risks associated with the chosen intervention may require more frequent evaluations.

Any change in physical or psychological response will be reported to the RN. The RN will determine if medical intervention is required or if criteria for release have been met.

8. Simultaneous Use of Restraint and Seclusion[9]

A patient in restraint and seclusion simultaneously requires a higher level of monitoring:

a. Continuous, uninterrupted monitoring, face-to-face by a specifically assigned staff member with demonstrated competence in close proximity to the patient for at least the first hour.
b. After the first hour, continuous uninterrupted monitoring, by a specifically assigned staff member with demonstrated competence using both video and audio equipment, with monitoring done in close proximity to the patient so as to allow emergency intervention if a problem arises. The use of video and audio equipment does not eliminate the need for frequent monitoring and assessment of the patient.

9. Face-to-face assessment by a Physician or Licensed Practitioner [10, 11]

a. A face-to-face assessment by a physician, licensed practitioner, RN or physician assistant with demonstrated competence, must be done within one hour of restraint or seclusion initiation or administration of medication to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. At the time of the face-to-face assessment, the licensed practitioner//physician/RN/PA will:
    1) Evaluate the patient's immediate situation
    2) Evaluate the patient's reaction to the intervention
    3) Evaluate the patient's medical and behavioral condition
    4) Evaluate the need to continue or terminate the restraint or seclusion

Note: A telephone call or telemedicine methodology does not constitute face-to-face assessment.

b. When the one-hour face-to-face is performed by a RN or physician assistant with demonstrated competence, the following must occur:
   1) The RN or physician assistant with demonstrated competence must consult the attending physician or licensed practitioner who is responsible for the care of the patient as soon as possible after the completion of the one-hour face-to-face evaluation. ("As soon as possible" is to be as soon as the attending physician is able to be reached by phone or in-person.) A consultation that is not conducted prior to renewal of the order would not be consistent with the requirement "as soon as possible."[12]
   2) The consultation should include, at a minimum, a discussion of the findings of the one-hour face-to-face evaluation, the need for other treatments, and the need to continue or discontinue the use of restraint or seclusion.
   3) If a patient who is restrained or secluded for aggressiveness or violence quickly recovers, has had a one-hour face-to-face evaluation by a competent registered nurse or physician assistant, , the physician or other licensed provider who is responsible for the care of the patient must still see the patient to perform an assessment within 24 hours after the initiation of restraint or seclusion.[13]

10. Care of the Patient/Plan of Care[14]

a. The plan of care will clearly reflect a loop of assessment, intervention, and evaluation for restraint, seclusion and medications.
b. Patients and/or families should be involved in care planning to the extent possible and made aware of changes to the plan of care**.**

11. Discontinuation of Restraint or Seclusion: The patient in restraint or seclusion is evaluated frequently and the intervention is ended at the earliest possible time.[15]

a. The time-limited order does not require that the application be continued for the entire period.
b. When an RN determines that the patient meets the criteria for release in the restraint order, restraints or seclusion are discontinued by staff with demonstrated competence.
c. Once restraints or seclusion are discontinued, a new order for restraint or seclusion is required to reapply or reinitiate.
d. A temporary**, directly-supervised,** release that occurs during patient care, e.g. toileting, feeding or range or motion, is not **considered a discontinuation of restraint or seclusion.**[16]

12. Documentation Requirements[17]

The medical record contains documentation of:

a. Assessment for risk for restraint or seclusion
b. Restraint or seclusion alternatives employed
c. The patient's condition or symptom(s) that warranted the use of the restraint or seclusion
d. Determination of effectiveness/ineffectiveness of restraint or seclusion alternatives
e. Second-tier review of need for restraint or seclusion
f. Order for restraint or seclusion and any renewal orders for restraint or seclusion
g. Restraint or seclusion application/initiation
h. Family notification of restraint or seclusion use
i. Patient and family education regarding restraint or seclusion use
j. Assessment of the patient in restraint or seclusion
k. Monitoring of the patient in restraint or seclusion
l. Medical and behavioral evaluation for restraint or seclusion management of violent or self-destructive behavior
m. The patient's response to the intervention(s) used, including the rationale for continued use of the intervention
n. Modifications of the plan of care
o. Physician notification of changes in patient condition
p. Restraint or seclusion removal/termination
q. Documentation requirements related to deaths of patients who were in or expired within 24 hours of being in restraint are located in Appendix C. Documentation requirements are also located in Appendix C for patients who expired within one week of being in restraint and it is reasonable to assume that the restraint contributed to the death.

13. Performance Improvement:

a. Data on the use of restraint and seclusion is collected to monitor appropriate use and to identify process improvement opportunities.
b. Data elements include:
    1) Number of patients restrained or secluded
    2) Number of restraint or seclusion hours
    3) Type of restraints
    4) Number of restraint or seclusion episodes
    5) Number of patient injuries/deaths while restrained or secluded
c. Data is trended, patterns of use, safety, and effectiveness are evaluated. Progress toward preventing, reducing and eliminating the use of restraints or seclusion is assessed.
d. Results of analysis are shared with facility leadership and appropriate committees, the Medical Executive Committee and the Board of Trustees/Governing Body.

e. If any inappropriate use of restraints or seclusion is identified, a root cause analysis will be performed, measures identified and implemented to remedy the issue(s).

14. Hospital CMS Reporting Requirements:[18]

The hospital must report the following information to CMS Regional Office electronically.

In accordance with the requirements at 42 CFR 482.13(g), Death Reporting Requirements, all patient deaths associated with restraint and/or seclusion (except two-point soft wrist restraints that must be recorded in an internal hospital log or other system) are required to be reported to the Centers for Medicare and Medicaid Services (CMS) Regional Offices (RO) using the **electronic** Form CMS-10455, Report of a Hospital Death Associated with the Use of Restraint or Seclusion.

Reporting is required by all types of hospitals (including Psychiatric Hospitals, Rehabilitation Hospitals, Long Term Care Hospitals, Short Term Acute Care Hospitals) and Critical Access Hospital (CAH) Rehabilitation and/or Psychiatric Distinct Part Units (DPUs).

The report must be submitted no later than the close of business on the next business day following knowledge of a patient's death:

1) Each death that occurs while a patient is in seclusion or restraint (with the exception of soft, non-rigid, cloth-like material restraints used on the patient's wrist[s], specific requirements apply to this group. See Appendix C);
2) Each death that occurs within 24 hours after the patient has been removed from seclusion or restraint (with the exception of soft, non-rigid, cloth-like material restraints used on the patient's wrist[s], specific requirements apply to this group. See Appendix C);
3) Each death known to the hospital that occurs within one week (occurring on day two through seven) after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint;
4) For deaths occurring outside the hospital, there may be a delay in this process based on when hospital became aware.

Hospitals must use the **electronic** Form CMS-10455 to report those deaths associated with restraint and/or seclusion that are required by 42 CFR §482.13(g) to be reported directly to their Centers for Medicare & Medicaid Services (CMS) Regional Office (RO). This requirement also applies to rehabilitation or psychiatric distinct part units (DPUs) in Critical Access Hospitals (CAHs).[11] Specific requirements for reporting and/or logging are located in Appendix C.

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REFERENCES:

1. The Joint Commission Comprehensive Accreditation Manual for Hospitals, Accreditation Requirements (2020) (TJC) Standard PC.03.05.01
2. HCA Healthcare Best Practice
3. TJC PC.03.05.05; Centers for Medicare & Medicaid Services State Operations Manual: Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals (2020) (CMS) §482.13(e)(5)
4. TJC PC.03.05.05 Element of Performance (EP) 2; CMS §482.13(e)(6)
5. TJC PC.02.01.03 EP20
6. CMS §482.13(e)(7)
7. TJC PC.03.05.05; CMS §482.13(e)(8); CMS §482.13(e)(8)(i); §482.13(e)(8)(ii)
8. TJC PC.03.05.07; CMS §482.13(e)(10)
9. TJC PC.03.05.13; CMS §482.13(e)(15)
10. TJC PC.03.05.17 EP3
11. TJC PC.03.05.11; CMS §482.13(e)(12)(i-ii)
12. TJC PC.03.05.11 EP1; TJC PC.03.05.11 EP2; CMS §482.13(e)(14)
13. CMS §482.13(e)(12)(i) Interpretive Guidelines
14. CMS §482.13(e)(4)(i) Interpretive Guidelines
15. CMS §482.13(e)(9)
16. CMS §482.13(e)(6) Interpretive Guidelines
17. CMS §482.13(e)(16)
18. CMS §482.13(g)
19. CMS Ref S&C: 14-27-Hospital-CAH/DPU May 9, 2014 https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-27.pdf
20. APNA Standards of Practice: Seclusion and Restraint Revised April 2014 https://www.apna.org/i4a/pages/index.cfm?pageid=3730
21. CMS QSO-20-04-Hospital-CAH DPU https://www.cms.gov/files/document/qso-20-04-hospital-cah-dpu

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APPENDIX A: TRAINING REQUIREMENTS

A. Direct Care Staff [1]

Staff will demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment and providing care for a patient in restraint or seclusion. Training will be provided to all staff designated as having direct patient care responsibilities (the facility to list), including contract or agency personnel. In addition, if hospital/ASC security guards or other non-healthcare staff (the facility to list) assist direct care staff, when requested, in the application of restraint or seclusion, the security guards, or other non-healthcare staff (as defined by the facility) are also expected to be trained and able to demonstrate competency in the safe application of restraint and seclusion. Training will occur:

1. Before performing restraint application, implementation of seclusion, monitoring, assessment and providing care for a patient in restraint or seclusion,
2. As part of orientation, and
3. On a periodic basis to ensure staff possess requisite knowledge and skills to safely care for restrained or secluded patients. Once initial training takes place, training must be provided frequently enough to ensure that staff possesses the requisite knowledge and skills to safely care for restrained or secluded patients in accordance with the regulations.
4. The results of skills and knowledge assessment, new equipment, or QAPI data may indicate a need for targeted training or more frequent or revised training.

B. Staff who conduct the one hour face-to-face evaluation[2]

The purpose of the one-hour face-to-face evaluation is to complete a comprehensive review of the patient's condition and determine if other factors such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient's violent or self-destructive behavior.

Training for the RN or PA who conduct the one-hour face-to-face will include:

1. Application of restraints.
2. Implementation of seclusion.
3. Monitoring, assessment and providing care for a patient in restraint or seclusion, including:
   a. The patient's immediate situation
   b. The patient's reaction to the intervention

c. The patient's medical and behavioral condition
d. The need to continue or terminate the restraint and seclusion

C. Physicians and other licensed practitioners authorized to order restraint
Physicians and other licensed practitioners authorized to order restraint will have a working knowledge of this policy on the use of restraint and seclusion.[3]

D. Individuals Providing Training
Individuals providing training will be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors for the populations served. In addition, these individuals will demonstrate a high degree of knowledge regarding all the requirements as set forth in this policy and procedure. There will be documentation to ensure that the individuals providing education and training have the appropriate qualifications required.[4]

Training Content

A. Restraint and Seclusion
All staff, including contract or agency personnel designated as having direct patient care responsibilities, will receive training in identifying patient and staff behaviors, events and environmental factors that may trigger circumstances that require the use of restraint or seclusion. Education and training will be based on the specific needs of the patient populations served. For example, staff who routinely provide care for patients who exhibit violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others (such as an emergency department or on a psychiatric unit) may receive more in-depth training than staff routinely providing medical/surgical care.[5]

B. Nonphysical Interventional Skills
Staff will be trained and able to demonstrate competency in the use of nonphysical interventional skills. These alternative techniques include redirecting the patient, engaging the patient in constructive discussion or activity or otherwise assisting the patient to maintain self-control and to avert escalation. Training will address application of nonphysical interventions based on the assessment of the individual patient's responses.[6]

C. Least Restrictive Interventions

Staff will be trained and able to demonstrate competency in choosing the least restrictive intervention based on the individualized assessment of the patient's medical or behavioral status or condition. Safe patient care requires looking at the patient as an individual and assessing the patient's condition, needs, strengths, weaknesses, and preferences and tailoring interventions to individual patient's needs after weighing factors such as the patient's condition, behaviors, history, and environmental factors.[7]

D. Safe Application

Staff will be trained and able to demonstrate competency in the safe application of all types of restraint and seclusion used in this facility including training to recognize and respond to signs of physical and psychological distress (e.g., positional asphyxia).[8]

E. Necessity of Restraint

Staff will be trained and able to demonstrate competency in identification of specific behavioral changes that may indicate that restraint or seclusion is no longer necessary and can be safely discontinued.[9]

F. Monitoring

Staff will be trained and able to demonstrate competency in monitoring the physical and psychological well-being of a patient who is restrained or secluded. This training will include but will not be limited to: respiratory and circulatory status, skin integrity, vital signs, and any special requirements identified by the facility associated with the one-hour face-to-face evaluation.[10]

G. First Aid

Staff will be trained and able to demonstrate competency in first aid techniques for patients in restraint or seclusion who are in distress or injured. The patient populations will be assessed to identify potential scenarios and develop training to address those scenarios. For example, for patients who are found hanging in a vest restraint, a restrained patient choking on food, a secluded and suicidal patient found hanging, a secluded suicidal patient who has cut himself, etc. Staff will be trained and certified in the use of cardiopulmonary resuscitation and periodically recertified.[11]

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[1] CMS §482.13(f)(1)(i)-(iii)
[2] CMS §482.13(e)(12)(ii); CMS §482.13(f)(1)(i)-(iii)

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[3] CMS §482.13(e)(11); CMS §482.13(f)(2)(i)
[4] CMS §482.13(f)(3)
[5] CMS §482.13(f)(2)(i)
[6] CMS §482.13(f)(2)(ii)
[7] CMS §482.13(f)(2)(iii)
[8] CMS §482.13(f)(2)(iv)
[9] CMS §482.13(f)(2)(v)
[10] CMS §482.13(f)(2)(vi)
[11] CMS §482.13(f)(2)(vii)

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APPENDIX B: ALTERNATIVES TO RESTRAINT OR SECLUSION

A. Psychosocial Alternatives

Diversion
Family interaction
Orientation
Pastoral visit
Reassurance
Reading
Relaxation techniques
Interpreter services
Personal possessions available
Quiet area
One-on-one discussion
Decreased stimulation
Change in environment
Re-establishing communication
Setting limits

B. Environmental Alternatives

Commode at bedside
Decreased noise
Music/TV
Night light
Room close to nursing station
Call light within reach
Bed alarm in use
Specialty low bed
Sensory aids available (glasses, hearing aid)
Decreased stimulation
Providing a quiet area
Physical activity orientation

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C. Physiological Alternatives

Toileting
Fluids/nutrition/snack
Positional devices
Pain intervention
Assisted ambulation
Re-positioning
Rest/sleep
Providing assistance
Additional warmth
Decreased temperature
Check lab values
Pharmacy consult

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APPENDIX C: HOSPITAL CMS REPORTING REQUIREMENTS[1]

A. Hospitals (meaning all types of hospitals, including Psychiatric Hospitals, Rehabilitation Hospitals, Long Term Care Hospitals, and not just Short Term Acute Care Hospitals) and Critical Access Hospitals with rehabilitation and/or psychiatric Distinct Part Unit (DPUs) must now use Form CMS-10455, "Report of a Hospital Death Associated with Restraint or Seclusion," to report deaths associated with restraint and/or seclusion that are required by 42 CFR §482.13(g) to be reported directly to the CMS Regional Office. The hospital must report the following information to CMS Regional Office electronically, as determined by CMS Regional Office, no later than the close of business on the next business day following knowledge of the patient's death:

1. Each death that occurs while a patient is in restraint (with the exception of soft, non-rigid, cloth-like material restraints used on the patient's wrist(s), see reporting requirements for this group below) or seclusion
2. Each death that occurs within 24 hours after the patient has been removed from restraint (with the exception of soft, non-rigid, cloth-like material wrist(s) restraints used on the patient, see reporting requirements for this group below) or seclusion
3. Each death known to the hospital that occurs within one week (days two through seven) after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation. In a case where only two-point soft wrist restraints were used and there was no seclusion, it may be presumed that the patient's death was not caused by the use of restraints
4. Each death occurring outside the hospital within one week after use of restraint or seclusion where the intervention may have contributed to the patient's death. It is possible that the patient's death might occur outside the hospital and that the hospital might not learn of the patient's death, or that there might be a delay in the hospital's learning of the patient's death.
5. The staff must document in the patient's medical record the date and time the death was reported to CMS.
6. The report to the CMS Regional Office must be submitted no later than close of the next business day following the day in which the hospital knows of the patient's death. The report must include basic identifying information related to the hospital, the patient's

name, date of birth, date of death, name of the attending physician/practitioner, primary diagnosis(es), cause of death (preliminary in cases when final official cause of death is not yet available) and types of restraint or seclusion used. (After review of the submitted information, the Regional Office will determine whether an on-site investigation is warranted.)

B. When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

1. Any death that occurs while a patient is in such restraints
2. Any death that occurs within 24 hours after a patient has been removed from such restraints
3. The staff must document in the patient's medical record the date and time the death was:
   a. Recorded in an internal log or other system for deaths of patients in soft, non-rigid, cloth-like material wrist(s) restraints described.
4. Entries into the internal log or other system must be documented as follows:
   a. Each entry must be made not later than seven days after the date of death of the patient.
   b. Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).
   c. The information must be made available to CMS immediately upon request.

[1] CMS §482.13(g); TJC PC.03.05.19

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APPENDIX D: DEFINITIONS

The definitions of restraint use types are applicable in any setting in the facility and are not driven by diagnosis.

A. Physical restraint: Any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body to include immobilization or reduction of the ability of a patient to move his or her arms, legs, body, or head freely is considered a physical restraint. An object may be a restraint by functional definition, which is when an object restricts the patient's movement or access to his or her body. Under this definition, many commonly used facility devices and practices could meet this definition of a restraint (e.g., tucking in sheets very tightly, use of side rails to prevent a patient from voluntarily getting out of bed, holding a patient to prevent movement, pinning of mitts on infants, arm restraints and other wrappings that prevent infants, children and/or adults from removing invasive lines or reopening surgical sites, etc.) [1]

B. Seclusion: Seclusion may only be used for the management of violent or self-destructive behavior. Seclusion is not limited to confining an individual to an area but involuntarily confining him/her alone in a room or area where he/she is physically prevented from leaving. A situation where a patient is restricted to a room alone and staff is physically intervening to prevent the patient from leaving the room or giving the perception that threatens the patient with physical intervention if the patient attempts to leave the room/area is considered seclusion.

1. **Timeout:** The definition of seclusion does not apply to "timeout" which is an intervention in which the patient consents to being alone in a designated area for an agreed upon timeframe from which the patient is not physically prevented from leaving. Therefore, the patient can leave the designated area when the patient chooses. [2]

C. Drugs as restraints: A drug or medication, when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition, is considered a restraint. When medications are used as restraints, it is important to note that the decision as to whether they constitute restraint is not specific to the treatment setting, but to the situation the restraint is being used to address. A medication that is not being used as a standard treatment or in a dosage for the patient's

medical or psychiatric condition and that results in controlling the patient's behavior and/or in restricting his or her freedom would be a drug used as a restraint.
A "standard treatment" for a medication to be used to address a patient's medical or psychiatric condition would include the following:

1. The medication is used within the pharmaceutical parameters approved for it by the FDA and the manufacturer, for the indications it is manufactured and labeled to address, listed dosage parameters, etc.
2. The use of the medication follows national practice standards established or recognized by the appropriate medical community and/or professional medical association; and
3. Use of the medication to treat a specific patient's clinical condition is based on that patient's target symptoms, overall clinical situation and of the licensed practitioner's knowledge of that patient's expected and actual response to the medication.

An additional component of "standard treatment" for a medication is the expectation that the standard use of a psychotherapeutic medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around him/her than would be possible without the use of the medication. Psychotherapeutic medications are to enable, not disable. If a psychotherapeutic medication reduces the patient's ability to effectively or appropriately interact with the world around him/her, then the psychotherapeutic medication is not being used as a "standard treatment" for the patient's condition. [3]

D. Physical Escort: A physical escort would include a "light" grasp to escort the patient to a desired location. If the patient can easily remove or escape the grasp, this would not be considered physical restraint. However, if the patient cannot easily remove or escape the grasp, this would be considered physical restraint. [4]

E. Physical Holds: The regulation permits the physical holding of a patient for the purpose of conducting routine physical examinations or tests. However, patients do have the right to refuse treatment. This includes the right to refuse physical examinations or tests. Holding a patient in a manner that restricts the patient's movement against the patient's will is considered restraint. This includes holds that some members of the medical community may term "therapeutic holds." Many deaths have occurred while employing these practices. Physically holding a patient during a forced psychotropic medication procedure is considered a restraint. If the patient is in a physical hold, a second staff person is assigned to observe the patient to ensure safety and the patient's airway is not compromised. [5]

F. Physical Holding for Forced Medications: The application of force to physically hold a patient, in order to administer a medication against the patient's wishes, is considered restraint. The patient has a right to be free of restraint and also has a right to refuse medications, unless a court has ordered medication treatment. A court order for medication treatment only removes the patient's right to refuse the medication. Additionally, in accordance with State law, some patients may be medicated against their will in certain emergency circumstances. However, in both of these circumstances, health care staff is expected to use the least restrictive method of administering the medication to avoid or reduce the use of force, when possible. The use of force in order to medicate a patient, as with other restraint, must have a physician's order prior to the application of the restraint (use of force). If physical holding for forced medication is necessary with a violent patient, the one-hour face-to-face evaluation requirement would also apply. In certain circumstances, a patient may consent to an injection or procedure, but may not be able to hold still for an injection, or cooperate with a procedure. In such circumstances, and at the patient's request, staff may "hold" the patient in order to safely administer an injection (or obtain a blood sample or insert an intravenous line, if applicable) or to conduct a procedure. This is **not** considered restraint. [6]

G. Weapons: CMS regulations specifically state that the use of weapons (within HCA Healthcare facilities weapons include but are not limited to pepper spray, mace, nightsticks, Tasers, stun guns, batons, handcuffs) in the application of restraint would be considered law enforcement restraint devices versus a safe appropriate health care intervention. The use of weapons by security staff is considered a law enforcement action, not a health care intervention. CMS does not support the use of weapons by any hospital/ASC staff as a means of subduing a patient in order to place that patient in restraint or seclusion. **If a weapon is used by security or law enforcement personnel on a person in a hospital/ASC (e.g., patient) to protect people or hospital property from harm, the situation should be handled as a criminal activity, law enforcement staff should enact the use of the weapon (not hospital contractors or employees) and the perpetrator be placed in the custody of local law enforcement.** [7]

H. Licensed Practitioner: A licensed practitioner (for the purpose of restraint ordering) is any practitioner permitted by state law and by facility policy with the authority to independently order restraints or seclusion for patients. This authority to order restraint/seclusion and perform or delegate face-to-face assessment must be in the scope of the individual's license and consistent with individually-granted clinical privileges at the facility.[8]

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I. Restraints with Heightened Risk: Vest restraints which tie crisscross have proven to contribute to patient injury and should not be used within HCA Healthcare facilities.[9] The FDA published a Public Health Notification on Vail Products in March 25, 2005, recommending that facilities stop using Vail beds.[10] Alternative beds should be chosen from the HCA Healthcare approved list. If another manufacturer is chosen, the facility must ensure that beds have been checked for possible entrapment zones prior to putting them into service. Entrapment zones include, but are not limited to, areas between the side rails and the mattress, between the mattress and the canopy in places where the rails do not extend, and areas between the end rails and the mattress.

J. Restraint Episode: A restraint episode is calculated from the date/time the restraint is applied to the date/time the restraint is discontinued. If there are multiple applications of restraint and only one discontinue date/time this would be calculated as one episode.

K. Side rails considered restraint: Using side rails to prevent a patient from voluntarily getting out of bed would be considered a restraint. The use of side rails is inherently risky, particularly if the patient is elderly or disoriented. Frail elderly patients may be at risk for entrapment between the mattress or bed frame and the side rail. Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail and exit the bed. When attempting to leave the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if the patient had fallen from the height of a lowered bed without raised side rails. In short, the patient may have an increased risk for a fall or other injury by attempting to exit the bed with the side rails raised. The risk presented by side rail use should be weighed against the risk presented by the patient's behavior as ascertained through individualized assessment. (See Exclusion to Restraint Section)

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Exceptions to the Definition of Restraints:

1. **Exclusion to Restraint:**

   Side rails not considered restraint
   A restraint does not include methods that protect the patient from falling out of bed. Examples include raising the side rails when a patient is: on a stretcher, recovering from anesthesia, sedated, experiencing involuntary movement, or on certain types of therapeutic beds to prevent the patient from falling out of the bed. A therapeutic bed includes beds that constantly move to improve circulation or prevent skin breakdown. The use of side rails in these situations protects the patient from falling out of bed and, therefore, would not be considered restraint.

   When a patient is placed on **seizure precautions** and all side rails are raised, the use of side rails would not be considered restraint. The use of padded side rails in this situation should protect the patient from harm, including falling out of bed should the patient have a seizure.

   Placement in a crib with raised rails is an age-appropriate standard safety practice for every infant or toddler. Therefore, placement of an infant or toddler in the crib with raised rails would not be considered restraint.

   If the patient is on a **stretcher** (a narrow, elevated, and highly-mobile cart used to transport patients and to evaluate or treat patients), there is an increased risk of falling from a stretcher without raised side rails due to its narrow width and mobility. In addition, because stretchers are elevated platforms, the risk of patient injury due to a fall is significant. Therefore, the use of raised side rails on stretchers is not considered restraint but a prudent safety intervention. Likewise, the use of a seat belt when transporting a patient in a wheelchair is not considered restraint.

2. Generally, if a patient can easily remove a device, the device would not be considered a restraint. In this context, **"easily remove"** means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the patient's physical condition and ability to accomplish objective (e.g., transfer to a chair, get to the bathroom in time).

3. **Use of voluntary mechanical support devices:**
Devices that are used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such mechanical support are not considered restraints. These may include, but are not limited to, orthopedic appliances and braces.[11]

4. **Use of Handcuffs:**
The use of handcuffs and other restrictive devices used by law enforcement who are not employed or contracted by the facility for custody, detention or other public safety reasons, and not for the provision of healthcare, is not governed by these standards. However, the use of such devices are considered law enforcement restraint devices and are not considered safe, appropriate health care restraint interventions for use by hospital staff to restrain patients.[12]

5. **Voluntary mechanical positioning or securing device:**
A medically necessary and voluntary positioning or securing device used to maintain the position, limit mobility, or temporarily immobilize the patient during medical, surgical, dental, or diagnostic procedures is not considered a restraint (e.g., backboards, surgical positioning, IV boards, radiotherapy procedures, protection of surgical and treatment sites in pediatric patients).[13]

6. **Age or developmentally-appropriate protective safety interventions:**
Devices such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails and crib covers, that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler or preschool-aged child, are not considered restraints. [14]

7. **Recovery from anesthesia:**
   Recovery from anesthesia that occurs when the patient is in the intensive care unit or recovery room is considered part of the surgical procedure and is not considered restraint. Recovery from anesthesia would be defined by the organization (i.e., Aldrete score).[15]

   Note: However, if the intervention is maintained when the patient is transferred to another unit or recovers from the effects of anesthesia (whichever occurs first), a restraint order would be necessary and the requirements related to restraint use should be followed. In addition, if the patient presents to the surgical area either Inpatient, Outpatient, or Ambulatory Surgical Center, in restraints prior to surgery, the restraint standards would apply.

8. **Protective devices or equipment:**
   Equipment, such as helmets, are not considered restraints if they are easily removed by the patient.[16]

9. **Behavior management:**
   Behavior management and treatment interventions should be therapeutic interventions that foster adaptive behaviors. They should not be used exclusively for behavior control. The use of mechanical restraint and seclusion as treatment interventions for behavior management is prohibited and should only be considered for patients who exhibit intractable behavior that is severely self-injurious or injurious to others and who have not responded to traditional interventions and who are unable to maintain self-safety.[17] The hospital does not use restraint or seclusion as a means of coercion, discipline, convenience, or staff retaliation.[18]

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[1] CMS §482.13(e)(1)(i)(A)
[2] CMS §482.13(e)(1)(ii)
[3] CMS §482.13(e)(1)(i)(B)
[4] CMS §482.13(e)(1)(i)(C)
[5] CMS §482.13(e)(1)(i)(C)
[6] CMS §482.13(e)(1)(i)(C)
[7] CMS §482.13(e)
[8] CMS §482.13(e)(5)
[9] HCA Healthcare Best Practice

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[10] FDA Public Health Notification: Vail Products Enclosed Bed Systems, Original Date March 25, 2005 and Updated June 24, 2005 & December 4, 2007
[11] CMS §482.13(e)(1)(i)(C)
[12] CMS §482.13(e)
[13] CMS §482.13(e)(1)(i)(C)
[14] CMS §482.13(e)(1)(i)(C)
[15] CMS §482.13(e)(1)(i)(C)
[16] CMS §482.13(e)(1)(i)(C)
[17] TJC PC.01.03.03
[18] TJC PC. 03.05.01


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